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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/438,994	11/12/99	FORT, J	6487.US.01

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EXAMINER	
PULLIAM, A	
ART UNIT	**PAPER NUMBER**
1615	5

DATE MAILED: 08/08/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/438,994	Applicant(s) FORT, ET AL.	
	Examiner Amy E Pulliam	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☒ Responsive to communication(s) filed on *10 February 2000* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-23* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 November 1999* is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Receipt is acknowledged of the Declaration an Information Disclosure Statement, received February 7, 2000 and February 10, 2000, respectively.

Drawings

The drawings are objected to because of the reasons specified on the attached PTO 948. Correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 8-10, 13-15, 18, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,773,025 to Baichwal (hereinafter Baichwal). Baichwal discloses an oral solid dosage form comprising particles of a therapeutically active medicament in amorphous form, and the process of preparing the composition (c 28, claims 1, 2, and 3) . In addition Baichwal discusses in great detail that in some embodiments, the insoluble medicament is dispersed into a water soluble carrier to form a solution or dispersion, which is referred to as a "solid dispersion." These types of dispersions provide improved solubility characteristics for otherwise insoluble

medicaments. Baichwal cites a known definition of a solid dispersion as "the dispersion of one or more active ingredients in an inert carrier or matrix at solid state prepared by the melting, solvent, or melting-solvent method." (c 6, l 50-60). Baichwal further discloses that the carrier discussed above, used to prepare a solid dispersion, comprises a pharmaceutically acceptable wetting agent and a mixed surfactant, such as sodium lauryl sulfate/ polyethylene glycol systems (c 7, l 19-28 and c 28, claim 3). Baichwal also discloses the inclusion of gelling agents, such as HPMC (c 5, l 35-45 and c 28, claim 7). Baichwal further discloses that the solid dispersion can further be compressed into a tablet (c 29, claim 13), or filled into a gelatin capsule (c 28, claim 12), or left as agglomerated particles (c 29, claim 16). Lastly, Baichwal discloses a method of making the above composition, involving combining the medicament in *amorphous* form with a wetting agent (PEG) [which is dissolved in a solvent such as water or ethanol, see c 7, l 31], in a manner as to create a solid dispersion, the mixing the resulting solid dispersion with a gelling agent (HPMC), in order to form agglomerated particles, wherein the amorphous form of the medicament affects the bioavailability of the oral dosage form (c 29, claim 19).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,773,025 to Baichwal as applied to claims 1, 2, 8-10, 13-15, 18, and 19 above. Baichwal discloses the same pharmaceutical dosage form as claimed by applicant. Baichwal does not incorporate the same active medicaments as those claimed by applicant. However, applicant states that the purpose of their invention is to improve bioavailability and aqueous dissolution properties of pharmaceuticals which exhibit poor aqueous solubility (applicant's specification, p 10, l 6-10). Baichwal has already invented a solid dispersion formulation, which can be made into any well known dosage form, which solves applicant's noted problems of poor dissolution and poor bioavailability. Specifically in column 2, beginning at line 62, Baichwal states that it is an object of his invention to provide a method for preparing a bioavailable formulation for a poorly soluble active medicament. And further, in column 3, line 11, Baichwal states that his invention provides acceptable bioavailability of an otherwise poorly bioavailable therapeutic active agent. Therefore, although Baichwal does not specifically disclose the drugs claimed by applicant in his formulation, it is the position of the examiner that varying the drug used in the formulation would have been obvious to one of ordinary skill in the art. One of ordinary skill in the art would have been motivated to use any drug with poor solubility and bioavailability in the formulation disclosed by Baichwal, because Baichwal teaches that his formulation solves those two very problems. The expected results would be a successful oral dosage form, with acceptable solubility and bioavailability. Therefore, the invention as a whole would have

been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,773,025 to Baichwal as applied to claims 1-19 above in view of the PDR. Further, Baichwal also does not teach the uses of the drugs claimed by applicant. However, it is the position of the examiner that the methods of treatment claimed in claims 20-23, are simply nominal treatments. In other words, HIV protease inhibitors are used to treat HIV infection, as fenofibrate is used to treat hyperlipedemic, and griseofulvin is used to treat fungal infections. The PDR is relied upon to show that the above uses are well known. Therefore, it would have been obvious to one of ordinary skill in the art to use these drugs, in Baichwal's formulation, for their well known purpose. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Election/Restrictions

This application contains claims directed to the following patentably distinct species of the claimed invention: HIV protease inhibitor, fenofibrate, and griseofulvin.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 2, 8-10, 13-15, 18, and 19 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is (703) 308-4710. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7922 for regular communications and (703) 308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Amy E. Pulliam
Patent Examiner
Art Unit 1615
August 2, 2000

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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